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APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 01/15/99 J 09/232,880 XU 210121.42806 **EXAMINER** HM12/0302 DAVID J MAKI HARRIS, A SEED AND BERRY ART UNIT PAPER NUMBER 6300 COLUMBIA CENTER 701 FIFTH AVENUE 1642 SEATTLE WA 98104-7092 **DATE MAILED:** 03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. **09/232,880**

Applicant(s)

Examiner

Alana M. Harris, Ph. D.

Group Art Unit

1642

Xu et al.



Responsive to communication(s) filed on	
☐ This action is FINAL .	
Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay/035 C.D. 11, 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire	
Disposition of Claim	
	is/are pending in the applicat
Of the above, claim(s)	_ is/are withdrawn from consideration
☐ Claim(s)	is/are allowed.
☐ Claim(s)	is/are rejected.
☐ Claim(s)	is/are objected to.
Claims <u>1-25</u> are subject	to restriction or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on	
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152 SEE OFFICE ACTION ON THE FOLLOWING PAGES	

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method for determining the presence or absence or monitoring the progression of prostate cancer in a patient using a binding agent, classified in class 435, subclass 7.1.
- II. Claims 7-12, drawn to a method for determining the presence or absence or monitoring the progression of prostate cancer in a patient using an oligonucleotide, classified in class 435, subclass 6.
- III. Claims 13-21, drawn to an isolated antibody and the kit comprising the said antibody, classified in class 530, subclass 387.1.
- IV. Claims 23-25, drawn to an oligonucleotide, classified in class 536, subclass 23.1.
- 2. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I and II differ in the method objectives, method steps and parameters and in the reagents used.

Groups III and IV are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

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Inventions of Group II and of Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP. § 806.05(h)). In the instant case the antibody of Group III can be used in *in vivo* treatment methods.

Inventions of Group II and of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP. § 806.05(h)). In the instant case the oligonucleotide of Group IV can be used in *in vivo* treatment methods.

3. Groups I and III are drawn to antibodies to polypeptides encoded by SEQ ID NO:2-3, 5-107, 109-11, 115-117, 173-175, 177, 179-228, 229-305, 307-326, 328, 330 or 332-335 and methods of using said antibodies. Each antibody is a structurally and functionally different product and the examination of more than one sequences would result in an undue search burden on the PTO. Thus, with the election of Group I or III, the applicant is required to select one of SEQ ID NO:2-3, 5-62, 66-107, 109-111, 115-171, 173-175, 177, 179-207, 209, 220, 222-225, 227-305, 307-326, 328, 330 or 332-335 for examination.

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probes and/or primers).

4. Groups IV and II is drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than ten individual, independent, and distinct nucleotide sequences in alternative form. Accordingly, Groups II and IV are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). Thus, with the election of either Group II or Group IV, applicant is required to specify no more than ten specific nucleotide sequences from SEQ ID NO:2-3, 5-107, 109-111, 115-171, 173-175, 177, 179-305, 307-326, 328, 330 or 332-335 for examination. This requirement is made under O.G. Notice 1192 O.G. 68 (November 19, 1996), as the examination of more than ten sequences in one application would result in an undue search burden on the PTO. The search of the no more than ten selected sequences may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric

- 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 6. Attempts to reach David J. Maki by telephone on 3/1/00 to request an oral election to the above restriction requirement were unsuccessful.

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Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37)

CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

fee required under 37 CFR 1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Alana M. Harris, whose telephone number is (703) 306-5880.

NANCY A. JOHNSON, PH.D.

PRIMARY EXAMINER